


Please type a plus sign (+) in this box 

#2


PTO/SB/08B (10/99)  
Approved for use through 10/31/99. OMB 0651-00  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				<b>Complete If Known</b>	
Sheet 1 Of 9		Application Number		09/419,849	
		Filing Date		October 19, 1999	
		First Named Inventor		Krivitski, N	
		Group Art Unit		2855	
		Examiner Name		Dickens	
		Attorney Docket Number		86017.000010	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. 1	Number	Kind Code 2 (if Known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
OP		5,720,284		Aoyagi et al.	02-24-1998	
OP		4,832,484		Aoyagi et al.	05-23-1989	
OP		4,777,958		Ophir	10-18-1988	
OP		4,797,655		Orndal et al.	01-10-1989	
OP		4,508,622		Polaschegg et al.	04-02-1985	
OP		5,230,341		Polaschegg	07-27-1993	
OP		5,100,554		Polaschegg	03-31-1992	
OP		4,938,873		Rossi	07-03-1990	
OP		5,642,734		Ruben et al.	07-01-1997	
OP		5,803,908		Steuer et al.	09-08-1998	
OP		4,596,550		Troutner	06-24-1986	
OP		4,231,366		Schael	11-04-1980	
OP		4,923,598		Schal	05-08-1990	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. 1	Office 3	Number 4	Kind Code 5 (if Known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T 6
OP			WO 94/27495		Steuer et al.	12-08-1994		
OP			WO 98/17193		Steuer et al.	04-30-1998		
OP			521891		Verkhovskii et al.	07-25-1976		
OP			255 478 A1		Zwonitz et al.	04-06-1988		
OP			0 089 003		Ishihara et al.	03-09-1983		
OP			0 018 817		Lale	11-12-1980		
OP			0 373 455		Rath et al.	06-20-2090		

Examiner Signature 	Date Considered	9/30/01
--	-----------------	---------

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3) 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

FEB 03 2000

TECHNOLOGY CENTER 2800

Please type a plus sign (+) in this box → ☐

PTO/SB/08B (10/5)  
Approved for use through 10/31/99. OMB 0651-00  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO				Complete If Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				Application Number	
				Filing Date	October 19, 1999
				First Named Inventor	
				Group Art Unit	
				Examiner Name	
Sheet	2	Of	9	Attorney Docket Number	86017.000010

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
Q	1	C. ALDRIDGE et al., The assessment of arteriovenous fistulae created for haemodialysis from pressure and thermal dilution measurements, Journal of Medical Engineering & Technology, May/June 1984, pp. 118-120, Vol. 8, No. 3	
Q		CHARLES B. ANDERSON, M.D. et al., Blood flow measurements in arteriovenous dialysis fistulas, Surgery, April 1977, pp. 459-461, Vol. 81, No. 4	
Q		DAVID A. OGDEN, M.D. et al., In vivo measurement of blood recirculation during "Y" type single needle dialysis, Journal of Dialysis, 1979, pp. 265-276, Vol. 3	
Q		LOUK F.I.J. OUDENHOVEN et al., Magnetic resonance, a new method for measuring blood flow in hemodialysis fistulae, Kidney International, 1994, pp. 884-889, Vol. 45	
Q		EMIL P. PAGANINI, MD, FACP, Adapting the dialysis unit to increased hematocrit levels, American Journal of Kidney Diseases, April 1995, pp. S12-S17, Vol. 25, No. 4, Suppl. 1	
Q		JAMES L. PORILE et al., Preservation of Vascular Access, Journal of the American Society of Nephrology, 1993, pp. 997-1003, Vol. 4, No. 4	
Q		STANLEY E. RITTGERS, PH.D. et al., Noninvasive blood flow measurement in expanded polytetrafluoroethylene grafts for hemodialysis access, Journal of Vascular Surgery, April 1986, pp. 635-642, Vol. 3, No. 4, The C.V. Mosby Company, St. Louis, Mo.	
Q		BARRY S. STRAUCH, MD, Forecasting thrombosis of vascular access with doppler color flow imaging, American Journal of Kidney Diseases, June 1992, pp. 554-557, Vol XIX, No. 6,	
Q		M. THOMAS et al., Measurement of vascular access recirculation without contralateral venous puncture, Nephron, 1992, pp. 224-225, Vol. 62	
Q		ZBYLUT J. TWARDOWSKI, MD, All currently used measurements of recirculation in blood access by chemical methods are flawed due to intradialytic disequilibrium or recirculation at low flow, American Journal of Kidney Diseases, December 1998, pp. 1046-1058, Vol. 32, No. 6	
Q		ZBYLUT J. TWARDOWSKI, Blood recirculation in intravenous catheters for hemodialysis, Journal of the American Society of Nephrology, 1993, pp. 1978-1981, Vol. 3, No. 12	
Q		JEFFREY SANDS et al., Access flow measured during hemodialysis, ASAIO Journal, January-February 1996, pp. 841-844, Vol. 42, No. 1, Lippencott-Raven Publishers	

Examiner Signature		Date Considered	9/30/01
--------------------	--	-----------------	---------

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) in this box → ☐

PTO/SB/08B (10/96)

Approved for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>Substitute for form 1449A/PTO</b> <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				<b>Complete If Known</b>		
				Application Number		
Sheet		3	Of	9	Filing Date	October 19, 1999
					First Named Inventor	
					Group Art Unit	
					Examiner Name	
					Attorney Docket Number	86017.000010

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. 1	Number	Kind Code 2 (if Known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
OP		4,181,610		Shintani et al.	01-01-1980	
OP		4,897,184		Shouldice et al.	01-30-1990	
OP		5,676,143		Simonsen et al.	10-14-1997	
OP		5,551,422		Simonsen et al.	09-03-1996	
OP		4,353,368		Slovak et al.	10-12-1982	
OP		4,856,321		Smalling et al.	08-15-1989	
OP		5,024,756		Sternby	06-18-1991	
OP		4,153,554		von der Heide et al.	05-08-1979	
OP		5,385,143		Aoyagi	01-31-1995	
OP		4,995,268		Ash et al.	02-26-1991	
OP		4,081,372		Atkin et al.	03-28-1978	
OP		3,990,973		Boag et al.	11-09-1976	
OP		3,964,479		Boag et al.	06-22-1976	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. 1	Office 3	Number 4	Kind Code 5 (if Known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T 6

Examiner Signature		Date Considered	9/30/01
--------------------	--	-----------------	---------

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3) 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → ☐

PTO/SB/08B (10/96)

Approved for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>Substitute for form 1449A/PTO</b> <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				<b>Complete If Known</b>	
				Application Number	
				Filing Date	October 19, 1999
				First Named Inventor	
				Group Art Unit	
				Examiner Name	
Sheet	4	Of	9	Attorney Docket Number	86017.000010

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
OP	1	ASAIO Journal, January-February 1996, p. 74, Vol. 42, No. 1, Lippincott-Raven Publishers	
OP	1	Journal of the American Society of Nephrology, September 1995, p. 501-502, Vol. 6, No. 3	
OP	1	Journal of the American Society of Nephrology, September 1996, p. 1419, Vol. 7, No. 9, Williams & Wilki	
OP	1	DANIEL SCHNEDITZ et al., Measurement of access flow during hemodialysis using the constant infusion approach, ASAIO Journal, 1998, pp. 74-81	
OP	1	RICHARD A. SHERMAN, MD et al., Assessment of a two-needle technique for the measurement of recirculation during hemodialysis, American Journal of Kidney Diseases, July 1991, pp. 80-83, Vol. I. XVIII,	
OP	1	RICHARD A. SHERMAN, MD et al., Rate-related recirculation: The effect of altering blood flow on dialyzer recirculation, American Journal of Kidney Diseases, February 1991, pp. 170-173, Vol. XVII, No. 2	
OP	1	RICHARD A. SHERMAN, MD et al., Recirculation reassessed: The impact of blood flow rate and the low-flow method reevaluated, American Journal of Kidney Diseases, June 1994, pp. 846-848, Vol. 23, No.	
OP	1	RICHARD A. SHERMAN, MD, The measurement of dialysis access recirculation, American Journal of Kidney Diseases, October 1993, pp. 616-621, Vol. 22, No. 4	
OP	1	MARK C. SHU et al., Flow phenomena in compliant and noncompliant arteriovenous grafts, ASAIO Transactions, July - September 1988, pp. 519-523, Vol. 34, No. 3	
OP	1	ROBERT R. STEUER et al., Enhanced fluid removal guided by blood volume monitoring during chronic hemodialysis, Artificial Organs, 1998, pp. 627-632, Vol. 22, No. 8	
OP	1	ROBERT R. STEUER et al., Poster Session - Renal 2: Hematocrit as an indicator of blood volume and a predictor of intradialytic morbid events, ASAIO Journal, July - September 1994, pp. M691-M696, Vol. 40,	
OP	1	ROBERT R. STEUER et al., Reducing symptoms during hemodialysis by continuously monitoring the hematocrit, American Journal of Kidney Diseases, April 1996, pp. 525-532, Vol. 27, No. 4	

Examiner Signature		Date Considered	9/30/01
--------------------	--	-----------------	---------

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → ☐

PTO/SB/08B (10/96)

Approved for use through 10/31/99. OMB 0651-0031


Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>Substitute for form 1449A/PTO</b> <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				<b>Complete If Known</b>		
				Application Number		
Sheet		5	Of	9	Filing Date	October 19, 1999
					First Named Inventor	
					Group Art Unit	
					Examiner Name	
					Attorney Docket Number	86017.000010

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. 1	Number	Kind Code 2 (if Known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
CP		4,966,691		Brous	10-30-1990	
CP		5,553,615		Carim et al.	09-10-1996	
CP		4,650,458		Dahlberg et al.	03-17-1987	
CP		4,391,124		Drost et al.	07-05-1983	
CP		4,434,648		Drost et al.	03-06-1984	
CP		4,123,353		Hakansson et al.	10-31-1978	
CP		5,312,550		Hester	05-17-1994	
CP		3,640,271		Horton	02-08-1972	
CP		5,526,808		Kaminsky	06-18-1996	
CP		5,690,104		Kanemoto et al.	11-25-1997	
CP		4,136,563		Mueller et al.	01-30-1979	
CP		4,432,231		Napp et al.	02-21-1984	
CP		5,685,989		Krivitski et al.	11-11-97	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. 1	Office 3	Number 4	Kind Code 5 (if Known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T 6

Examiner Signature		Date Considered	9/30/01
--------------------	---	-----------------	---------

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3) 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign  inside this box

PTO/SB/08B (10/96)

Approved for use through 10/31/99. OMB 0651-0031

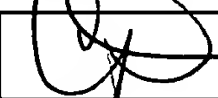
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<p>Substitute for form 1449A/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(use as many sheets as necessary)</p>				<b>Complete If Known</b>		
				Application Number		
Sheet		6	Of	9	Filing Date	October 19, 1999
					First Named Inventor	
					Group Art Unit	
					Examiner Name	
					Attorney Docket Number	86017.000010

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
Q	1	JOHN C. VAN STONE, MD et al., Detection of hemodialysis access outlet stenosis by measuring outlet resistance, American Journal of Kidney Diseases, April 1994, pp. 562-568, Vol. 23, No. 4	
Q	1	DAVID W. WINDUS, MD, Permanent vascular access: A nephrologist's view, American Journal of Kidney Diseases, May 1993, pp. 457-471, Vol. 21, No. 5	
Q	1	VON G. WITTENBERG et al., Interobserver-Variabilitat von dialyseshuntflubmessungen mit der farbkodierten duplexsonographie, Fortschr Rontgenstr, 1993, pp. 375-378	
Q	1	J.A. BARRA et al., Interet de la debimetric ultrasonique dans la surveillance post-operatoire et l'evolution des fistules arterio-veineuses pour l'hemodialyse chronique, Journal d'Urologie et de Nephrologie, 1997, pp. 519-525	
Q	1	ANATOLE BESARAB et al., Determinants of measured dialysis venous pressure and its relationship to true intra-access venous pressure, ASAIO Transactions, July - September 1991, pp. M270-M271, Vol. 37, No. 3	
Q	1	ANATOLE BESARAB et al., The relationship of recirculation to access blood flow, American Journal of Kidney Diseases, February 1997, pp. 223-229, Vol. 29, No. 2	
Q	1	Journal of the American Society of Nephrology, September 1995, p. 1484, Vol. 6, No. 3	
Q	1	PETER J. BOSMAN et al., Access flow measurements in hemodialysis patients: In vivo validation of an ultrasound dilution technique, Journal of the American Society of Nephrology, June 1996, pp. 966-969, Vol. 7, No. 6	
Q	1	JOHN D. BOWER et al., Circulatory function during chronic hemodialysis, ASAIO, pp. 373-377	
Q	1	B. CHARRA et al., A dye-dilution cardiac output technique for hemodialyzed patients with arteriovenous fistula, Kidney International, 1973, pp. 51-53, Vol. 3	
Q	1	A.K. CHEUNG, Stages of future technological developments in haemodialysis, Nephrol Dial Transplant, 1996, pp. 52-58, Vol. 11, Suppl. 8	
Q	1	VALERIE DE PRECIGOUT et al., Comparaison de differentes techniques de surveillance des abords vasculaires chez l'hemodialyse chronique, Nephrologie, 1994, pp. 87-90, Vol. 15, No. 2	

Examiner Signature		Date Considered	9/30/01
--------------------	---	-----------------	---------

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign inside this box ➡ +

PTO/SB/08B (10/96)  
Approved for use through 10/31/99. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<p>• Substitute for form 1449A/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p><i>(use as many sheets as necessary)</i></p>				<b>Complete If Known</b>	
Application Number					
Filing Date		October 19, 1999			
First Named Inventor					
Group Art Unit					
Examiner Name					
Attorney Docket Number		86017.000010			
Sheet	7	Of	9		

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Site	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
[Signature]	31	Journal of the American Society of Nephrology, September 1995, p. 1486, Vol. 6, No. 3	
[Signature]	✓	THOMAS A. DEPNER, Nephrology forum - Assessing adequacy of hemodialysis: Urea modeling, Kidney International, 1994, pp. 1522-1535, Vol. 45	
[Signature]	✓	ASAIO Journal, January - February 1996, p. 81, Vol. 42, No. 1	
[Signature]	✓	Journal of the American Society of Nephrology, September 1996, p. 1407, Vol. 7, No. 9	
[Signature]	✓	R.D. GLEED et al., Validation in the sheep of an ultrasound velocity dilution technique for haemodialysis graft flow, Nephrology Dialysis Transplantation, 1997, pp. 1464-1467, Vol. 12	
[Signature]	✓	ROBERT L. HESTER, Ph.D. et al., A new technique for determining recirculation in the ESRD Patient, Nephrology News & Issues, June 1993, pp. 44-45	
[Signature]	✓	ROBERT L. HESTER, Ph.D. et al., The determination of hemodialysis blood recirculation using blood urea nitrogen measurements, American Journal of Kidney Diseases, December 1992, pp. 598-602, Vol. XX, No. 6	
[Signature]	✓	N.A. HOENICH et al., A technique for the laboratory determination of recirculation in single needle dialysis, The International Journal of Artificial Organs, pp. 63-70, Vol. 16, No. 2	
[Signature]	✓	NICHOLAS ANDREW HOENICH et al., Technology and clinical application of large-bore and implantable catheters, Artificial Organs, pp. 276-282, Vol. 18, No. 4	
[Signature]	✓	JACOBO KELBER, MD et al., Factors affecting delivery of high-efficiency dialysis using temporary vascular access, American Journal of Kidney Diseases, July 1993, pp. 24-29, Vol. 22, No. 1	
[Signature]	✓	BARRY KIRSCHBAUM, MD et al., Study of vascular access blood flow by angiodynography, American Journal of Kidney Diseases, January 1995, pp. 22-25, Vol. 25, No. 1	
[Signature]	✓	H.W. KLEMPT et al., Ergebnisse der farbstoffverdünnungstechnik bei peripheren, arteriovenösen fisteln und hyperthyreosen, Eingegangen, January 1975, pp. 863-878, Vol. 64	

Examiner Signature	[Signature]	Date Considered	9/30/01
--------------------	-------------	-----------------	---------

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Please type a plus sign (+) inside this box → ☐

PTO/SB/08B (10/96)

Approved for use through 10/31/99. OMB 0651-0031


Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)				<b>Complete If Known</b>		
				Application Number		
Sheet		8	Of	9	Filing Date	October 19, 1999
					First Named Inventor	
					Group Art Unit	
					Examiner Name	
					Attorney Docket Number	86017.000010

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
OP	1	NIKOLAI M. KRIVITSKI, Ph.D. et al., Accuracy of dilution techniques for access flow measurement during hemodialysis, American Journal of Kidney Diseases, March 1998, pp. 502-508, Vol. 31, No. 3	
OP	1	Nephrology Dialysis Transplantation, September 1997, p. A129, Vol. 12, No. 9	
OP	1	Journal of the American Society of Nephrology, September 1997, p. 164A, Vol. 8	
OP	1	Journal of the American Society of Nephrology, September 1997, p. 155A, Vol. 8	
OP	1	Journal of the American Society of Nephrology, September 1995, p. 1496, Vol. 6, No. 3	
OP	1	NIKOLAI M. KRIVITSKI, Novel method to measure access flow during hemodialysis by ultrasound velocity dilution technique, ASAIO Journal, July-September 1995, pp. M741-M744, Vol. 41, No. 3	
OP	1	Journal of the American Society of Nephrology, September 1996, p. 1410, Vol. 7, No. 9	
OP	1	NIKOLAI M. KRIVITSKI, Theory and validation of access flow measurement by dilution technique during hemodialysis, Kidney International, 1995, pp.244-250, Vol. 48	
OP	1	ASIAO Journal, January - February 1996, p. 80, Vol. 42, No.1, Lippincott-Raven Publishers	
OP	1	D. KRPAN et al., Measurement of blood flow through AV-fistulae by means of Doppler sonography in regularly haemodialysed patients, 1992, pp.78-82, Vol. 14, No.2	
OP	1	KAZUYOSHI KUBOTA et al., Arteriovenous shunt flow measurement by ultrasonic duplex system, ASAIO Transactions, July-September 1987, pp.144-146, Vol. 33, No. 3	
OP	1	B.M.T. LANTZ et al., Determination of blood flow through arteriovenous fistulae and shunts, Acta Radiological Diagnosis, 1979, pp. 727-736, Vol. 20	

Examiner Signature		Date Considered	9/30/01
--------------------	---	-----------------	---------

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Please type a plus sign (+) inside this box → +

PTO/SB/08B (10/96)

Approved for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<p>Substitute for form 1449A/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(use as many sheets as necessary)</p>				<b>Complete If Known</b>	
				Application Number	
				Filing Date	October 19, 1999
				First Named Inventor	
				Group Art Unit	
				Examiner Name	
				Attorney Docket Number	86017.000010
Sheet	9	Of	9		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
OIPE JAN 31 2000 PATENT & TRADEMARK OFFICE	1	ROBERT M. LINDSAY et al., A comparison of methods for the measurement of hemodialysis access recirculation, ASAIO Journal, 1998, pp. 191-193	
OIPE	1	Journal of the American Society of Nephrology, September 1996, p. 1412, Vol. 7, No. 9	
OIPE	1	ROBERT M. LINDSAY et al., A device and a method for rapid and accurate measurement of access recirculation during hemodialysis, Kidney International, 1996, pp. 1152-1160, Vol. 49	
OIPE	1	ROBERT M. LINDSAY, Assessment of access recirculation during haemodialysis, Current Opinion in Nephrology and Hypertension, 1997, pp. 570-574, Vol. 6	
OIPE	1	ROBERT M. LINDSAY, Hemodialysis access blood flow rates can be measured by a differential conductivity technique and are predictive of access clothing, American Journal of Kidney Diseases, October 1997, pp. 475-482, Vol. 30, No. 4	
OIPE	1	F. LOPOT, Use of continuous blood volume monitoring to detect inadequately high dry weight, The International Journal of Artificial Organs, 1996, pp. 411-414	
OIPE	1	RICHARD E. MAY, Predictive measures of vascular access thrombosis: A prospective study, Kidney International, 1997, pp. 1656-1662, Vol. 52	
OIPE	1	D.A. OGDEN, Blood recirculation during hemodialysis with a coaxial counterflow single needle blood access catheter, ASAIO Transactions, April 20-21, 1979, pp. 325-327, Vol. 25	

Examiner Signature	Date Considered	9/30/01
--------------------	-----------------	---------

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → +

#3

PTO/SB/08A (10-96)  
App. for use through 10/31/99. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				<b>Application Number</b>	09/419,849
				<b>Filing Date</b>	October 19, 1999
				<b>First Named Inventor</b>	Krivitski, Nikolai M.
				<b>Group Art Unit</b>	
				<b>Examiner Name</b>	
<b>Attorney Docket Number</b>	86017.000010				
<b>Sheet</b>	1	<b>of</b>	1		

U.S. PATENT DOCUMENTS						
Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
<div style="position: relative; height: 100%;"><div style="position: absolute; top: 0; left: 0; right: 0; bottom: 0; border-left: 2px solid black; border-right: 2px solid black; transform: rotate(45deg);"></div><div style="position: absolute; top: 0; left: 0; right: 0; bottom: 0; border-left: 2px solid black; border-right: 2px solid black; transform: rotate(-45deg);"></div></div>		5,900,726		Brugger, et al.	—	—

O I P E  
NOV 01 2000  
PATENT & TRADEMARK OFFICE

RECEIVED  
NOV 20 2000  
TO 3700 MAIL ROOM

FOREIGN PATENT DOCUMENTS								
Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
<div style="position: relative; height: 100%;"><div style="position: absolute; top: 0; left: 0; right: 0; bottom: 0; border-left: 2px solid black; border-right: 2px solid black; transform: rotate(45deg);"></div><div style="position: absolute; top: 0; left: 0; right: 0; bottom: 0; border-left: 2px solid black; border-right: 2px solid black; transform: rotate(-45deg);"></div></div>								

RECEIVED  
NOV 27 2000  
TO 2800 MAIL ROOM

<b>Examiner Signature</b>	<b>Date Considered</b>
	9/30/01

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → +

PTO/SB/08B (10-96)

Approved for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>Substitute for form 1449B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>			
				Application Number		09/419,849	
				Filing Date		October 19, 1999	
				First Named Inventor		Krivitski, Nikolai M.	
				Group Art Unit			
				Examiner Name			
Sheet	/	of	/	Attorney Docket Number		86017.000010	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
[Signature]	1	Michael Simonsen, Ph.D., Innovation pace remains rapid in interventional cardiology, American Health Consultants®, Vol. 4 No. 5	
[Signature]	2	Michael Simonsen, Ph.D., Interventional radiology market is diverse and growing rapidly, American Health Consultants®, Vol. 5 No. 6	
[Signature]	3	A. Fronek, M.D., V. Ganz, M.D., Measurement of Flow in Single Blood Vessels Including Cardiac Output by Local Thermodilution, Circulation Research, Vol. VIII, January 1960	
[Signature]	4	Kenneth F. Hosle, Thermal-Dilution Technics, Circulation Research, Vol. I, March 1962	
<div style="border: 1px solid black; border-radius: 50%; width: 150px; height: 150px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"><div style="text-align: center;">OIPF NOV 01 2000 PATENT &amp; TRADEMARK OFFICE</div></div>			
<div style="display: flex; justify-content: space-between;"><div style="writing-mode: vertical-rl; transform: rotate(180deg);">RECEIVED NOV 27 2000 TC 2800 MAIL ROOM</div><div style="writing-mode: vertical-rl; transform: rotate(180deg);">RECEIVED NOV 20 2000 TC 3700 MAIL ROOM</div></div>			

Examiner Signature	[Signature]	Date Considered	9/30/01
--------------------	-------------	-----------------	---------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement. This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Approved for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

*(use as many sheets as necessary)*

Sheet	1	of	2
-------	---	----	---

**Complete if Known**

<b>Application Number</b>	09/419,849
<b>Filing Date</b>	October 19, 1999
<b>First Named Inventor</b>	Krivitski, Nikolai M.
Group Art Unit	
Examiner Name	
<b>Attorney Docket Number</b>	86017.000010

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

Examiner  
Signature

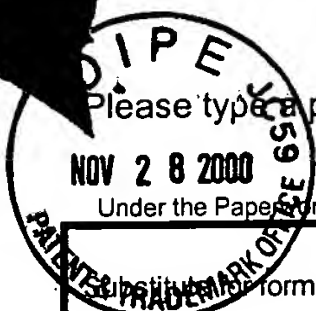
Date  
~~Considered~~

9/30/0,

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>. Unique citation designation number. <sup>2</sup>. See attached Kinds of U.S. Patent Documents. <sup>3</sup>. Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). <sup>4</sup>. For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>. Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.**



Please type a plus sign (+) inside this box → +

PTO/SB/08B (10-96)  
Approved for use through 10/31/99. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.



<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>			
				Application Number		09/419,849	
				Filing Date		October 19, 1999	
				First Named Inventor		Krivitski, Nikolai M.	
				Group Art Unit			
				Examiner Name			
				Attorney Docket Number		86017.000010	
Sheet	2	of	2				

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		JAMES L. LINZELL, PH.D, Measurement of Venous Flow by Continuous Thermodilution and its Application to Measurement of Mammary Blood Flow in the Goat, Circulation Research, Vol. XVIII, June, 1966	

Examiner Signature		Date Considered	9/30/01
-----------------------	--	--------------------	---------

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement. This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



App. for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

FEB 05 2001  
 DISCLOSURE  
 BY APPLICANT  
 PATENT & TRADEMARK OFFICE

Class/

10

*[Handwritten signature]*

+

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →

+

PTO/SB/08B (10-96)

Approved for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>Substitute for form 1449B/PTO</b> <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)  Sheet 2 of 4		<b>Complete if Known</b>	
		<b>Application Number</b>	09/419,849
		<b>Filing Date</b>	October 19, 1999
		<b>First Named Inventor</b>	Krivitski, Nikolai M.
		<b>Group Art Unit</b>	
		<b>Examiner Name</b>	
		<b>Attorney Docket Number</b>	86017.000010

**OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
CP	✓	J. SANDS, et al.; Transonic Hemodialysis Monitor; Difference Between Delivered and Prescribed Blood Flow (QB) in Hemodialysis; ASAIO '96	
CP	✓	GREENWOOD, R.N., ALDRIDGE, C. AND CATTELL, W.R., Serial Blood Water Estimations And In-Line Blood Viscometry: The Continuous Measurement Of Blood Volume During Dialysis Procedures; <i>Clinical Sciences</i> , (1984) 66. p. 575-583	
CP	✓	KAYE, M., LEMAITRE, P. AND O'REGAN, S., A New Technique For Measuring Blood Flow In Polytetrafluorethylene Grafts For Hemodialysis,	
CP	✓	O'REGAN, S., LEMAITRE, P. AND KAYE, M., Hemodynamic Studies In Patients With Expanded Polytetrafluorethylene (PTFE) Forearm Grafts. pp. 96-100	
CP	✓	PAULO ROCHA, MD, JEAN-CLAUDE KAHN, M.D. GERARD DONGRADI, M.D., BERNARD BARON, M.D. AND JEAN-PIERRE FENDLER, M.D., Arteriovenous Shunt Measured by Bolus Dye Dilution: Reproducibility and Comparison Between Two Injection Sites; Catheterization and Cardiovascular Diagnosis 11:473-481 (1985).	
CP	✓	CAROL L. MIRANDA, Increasing AV Fistulas for Hemodialysis Access, Dialysis: Access/Methods of Hemodialysis, #205, JASN, September 1995, Volume 6, Number 3	
CP	✓	DANIEL SCHNEDITZ AND THOMAS KANNER, A Sound Speed Sensor For The Measurement Of Total Protein Concentration. J. Account Soc. Am. 86 (6), December 1989 p. 2073-2080	
CP	✓	T. BUUR AND E.J. WILL, Maemodialysis Recirculation Measured Using A Femoral Artery Sample, Nephrol Dial Transplant (1994) 9: p. 395-398	
CP	✓	T.A. DEPNER AND N.M. KRIVITSKI, Influence of Access Blood Flow on Systemic Blood Flow in Hemodialysis Patients, JASN Vol. 8, p. 155A, 1997 (HD23A)	
CP	✓	THOMAS A. DEPNER AND NIKOLAI M. KRIVITSKI, Clinical Measurement of Blood Flow in Hemodialysis Access Fistulae and Grafts by Ultrasound Dilution, ASAIO; July-September 1995, Vol. 41, No. 3, Lippincott-Raven Publishers, U.S.A.. Journal, July-September 1995, Lippincott-Raven Publishers, Vol. 41, No. 3	
CP	✓	V.A DEL GROSSO AND C.W. MADER, Speed of Sound in Sea-Water Samples,	
CP	✓	L. FORSBERG. U. TYLEN, T. OLIN AND E. LINDSTEDT, Quantitative Flow Estimations Of Arteriovenous Fistulas With Doppler And Dye-Dilution Techniques, p. 465-468	
CP	✓	S. GOTTLIEB, E. GARCIA, S.B. COLD, AND B.A. VANDERWERF, Radiotracer Method For Nonsurgical Measurement Of Blood Flow In Bovine Graft Arteriovenous Fistulas, Proc. Dialysis Transplant Forum, 1976, p. 107108	

<b>Examiner Signature</b>		<b>Date Considered</b>	9/30/01
---------------------------	---	------------------------	---------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement. This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Please type a plus sign (+) inside this box → +

PTO/SB/08B (10-96)

Approved for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<p>Substitute for form 1449B/PTO</p> <p style="text-align: center;"><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p style="text-align: center;">(use as many sheets as necessary)</p>		<p style="text-align: center;"><b>Complete if Known</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%;">Application Number</td><td>09/419,849</td></tr><tr><td>Filing Date</td><td>October 19, 1999</td></tr><tr><td>First Named Inventor</td><td>Krivitski, Nikolai M.</td></tr><tr><td>Group Art Unit</td><td></td></tr><tr><td>Examiner Name</td><td></td></tr><tr><td>Attorney Docket Number</td><td>86017.000010</td></tr></table>		Application Number	09/419,849	Filing Date	October 19, 1999	First Named Inventor	Krivitski, Nikolai M.	Group Art Unit		Examiner Name		Attorney Docket Number	86017.000010
Application Number	09/419,849														
Filing Date	October 19, 1999														
First Named Inventor	Krivitski, Nikolai M.														
Group Art Unit															
Examiner Name															
Attorney Docket Number	86017.000010														
Sheet	3	of	4												

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
OP	1	JAMES F. GREENLEAF, PH.D, Tissue Characterization With UltraSound, Volume II, Results and Applications, CRC Press, Inc., Boca Raton, FL	
OP	1	DANIEL SCHNEDITZ, et al., Cardiopulmonary Recirculation in Dialysis, ASAIO Journal 1992, p. M-194-M-196;	
OP	1	E.L. BRADLEY, et al., The velocity of ultrasound in Human Blood Under Varying Physiologic parameters	
OP	1	GUYTON, Textbook of Medical Physiology, p. 287-288	
OP	1	NIKOLAI M. KRIVITSKI AND THOMAS A DEPNER, Development of a Method for Measuring Hemodialysis Access Flow: From Idea to Robust Technology; Research in Dialysis, p. 124-130	
OP	1	NIKOLAI M. KRIVITSKI AND THOMAS A DEPNER, Influencer of Access Bloow Flow on Systemic Blood Flow in Hemodialysis Patients; Dialysis: Methods of Hemodialysis and Vascular Acces, p. 155AS	
OP	1	M GERMAIN, Correlation of Weekly Access Blood Flow Rate and Access Stenosis and Clotting; Dialysis: Access/Methods of Hemodialysis; p. 1407.	
OP	1	NIKOLAI M. KRIVITSKI AND THOMAS A DEPNER, Access Flow Measured from Recirculation of Urea During Hemodialysis with Reversed Blood Lines; Dialysis: Access/Methods of Hemodialysis, #198	
OP	1	LEIF EKELEND, JAN GOTHLIN AND TORD OLIN, Arteriovenous Fistulae in Rabbit Kidney Studied by Dye-Dilution Technique and by Angiography; Scand J. Uron Nephrol 6: 84-90, 1972	
OP	1	JAN GOTHLIN ERIC LINSTEDT AND TORD OLIN, A Dye-Dilution Method for the Determination of Blood Flow in Cimino-Brescia Arteriovenous Fistulae, Copyright 1997 by the Williams & Williams Company	
OP	1	ROBERT L. HESTER, et al.; Non-Invasive Determination of Recirculation in the Patient on Dialysis; ASAIO Journal 1992, p. M190-193.	
OP	1	NIKOLAI M. KRIVITSKI, Blood Flow Measurement in PTFE Hemodialysis Grafts (HG) By Ultrasound Velocity Dilution (in Vitro Validation); Dialysis: Access/Methods of Hemodialysis	
OP	1	C. ALDRIDGE, et al., Instrument Design for the Bedside Assessment of Arteriovenous Fistulae in Haemodialysis Patients; Proc EDTNA-ERCA (1985) Vol. 14 p. 255-260	

Examiner Signature		Date Considered	9/30/01
--------------------	--	-----------------	---------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement. This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

4

of

4

**Complete if Known**

Application Number	09/419,849
Filing Date	October 19, 1999
First Named Inventor	Krivitski, Nikolai M.
Group Art Unit	
Examiner Name	
Attorney Docket Number	86017.000010

**OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
CD	1	N.M. KRIVITSKI, et al.; Vascular Access Flow Changes with Normal or Reversed Hemodialysis Blood Flow; ASAIO, January-February 1996, p. 80.	
CD	1	DANIEL SCHNEDITZ, et al.; On-Line Measurement of Blood Water Concentration in the Extracorporeal Circulation of Hemodialysis Patients; Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Vol. 13, No. 4, 1991	
CD	1	I.D. DANIELS, G.M. BERLYNE, R.H. BARTH, Blood Flow Rate and Access Recirculation in Hemodialysis; The International Journal of Artificial Organs, Vol. 15, No. 8, 1992, pp. 270-474.	
CD	1	P. CHANMEY, et al., Modelling Cardiopulmonary and Fistula Recirculation,	
CD	1	GUNNAR LINGARDH AND BO LUNDSTROM, Renal Blood Flow in Man Studies with Dye Dilution Method; Scandinavian Journal of Urology and Nephrology, Vol. 6, No. 1, 1972, p. 54-62	
CD	1	SHAHBUDIN H. RAHIMTOOLA, et al., Calculation of Cardiac Output from Indicator-Dilution Curves in the Presence of Mitral Regurgitation; <i>Circulation</i> , American Heart Association, Vol. XXXI, No. 4, 1965	
CD	1	C. NORRYD, et al.; Superior Mesenteric Blood Flow in Man Studies with a Dye-Dilution Technique; <i>Aeta Chir Scand</i> 141: 109-118, 1974	
CD	1	H. DENCKER, et al., Portal Circulation in Humans Studies by a Dye-Dilution Technique; <i>European Surgical Research</i> , Vol. 4, No. 2 (pp. 81-152), 1972	
CD	1	L. JORFELDT AND J. WAHREN, Leg Blood Flow During Exercise in Man, <i>Clinical Science</i> , 1971, 41, pp. 459-473.	
CD	1	R.N. GREENWOOD, et al., Assessment of Arteriovenous Fistulae From Pressure And Thermal Dilution Studies: Clinical Experience In Forearm Fistulae, <i>Clinical Nephrology</i> , Vo. 23, No. 4 - 1985 (pp. 189-197).	
CD	1	R. ANDRES, Measurement of Blood Flow and Volume in the Forearm of Man; With Notes on the Theory of Indicator-Dilution and on Production of Turbulence, Hemolysis and Vasodilation by Intra-Vascular Injection; <i>The Journal of Clinical Investigation</i> , Volume XXXIII, 1954, pp. 482-504.	
CD	1	JAN GOTHLIN, TORD OLIN, Dye Dilution Technique with Nephroangiography for the Determination of Renal Blood Flow and Related Parameters; <i>Acta Radiologica</i> , Vol. 14, Fasc. 1, January, 1973	
CD	1	J. WAHREN AND L. JORFELDT, Determination of Leg Blood Flow During Exercise in Man: An indicator-Dilution Technique based on Femoral Venous Dye Infusion; <i>Clinical Science and Molecular Medicine</i> (1973), 45, 135-146.	
CD	1	N. KRIVITSKI, et al.; Saline release method to measure access flow by ultrasound dilution during hemodialysis; <i>Dialysis: Methods of Hemodialysis and Vascular Access</i> , p. 164A	

Examiner  
SignatureDate  
Considered

9/30/01

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement. This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.